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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,718	10/17/2003	Jack D. Lemmon	M190.143.101	1756
7590 02/08/2006 Dicke, Billig & Czaja, PLLC Fifth Street Towers, Suite 2250 100 South Fifth Street Minneapolis, MN 55402			EXAMINER SNOW, BRUCE EDWARD	
			ART UNIT 3738	PAPER NUMBER
DATE MAILED: 02/08/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/688,718	Applicant(s) LEMMON, JACK D.	
	Examiner Bruce E. Snow	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31, 38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) 7, 14, 23, 29, 31 and 39 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 39 is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-13, 15-21, 25-28 and 30 is/are rejected.
- 7) ☒ Claim(s) 22 and 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's amendments and arguments filed 11/28/05 have been fully considered.

It is noted that applicant indicated claims 4-6 and 23 as now having the status of "withdrawn". Claim 4 does not positively claim a "stent", but only further defines the prosthetic heart valve described in the preamble and should not be withdrawn. Claims 5-6 depend from claim 4 and remain in prosecution. Claim 23 is correctly withdrawn directed to a non-elected species of sizers.

The rejection under 35 U.S.C. 102(b) as being clearly anticipated by Buchanan (2002/017384) has been withdrawn not teaching a continuous outer ring as now required by claim 1. Additionally, applicants amendments and arguments overcame the rejection under 35 U.S.C. 102(b) as being anticipated by Love.

The rejection of claim 1 as being unpatentable over Rhee in view of Love et al has been withdrawn because the outer ring 18 is not an end surface of the sizer body.

Election/Restrictions

Newly submitted claim 39 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Inventions 1 (claim 1) and 2 (claim 39) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In

the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because "undulating, contoured end surface". The subcombination has separate utility such as teaching or sales aid.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 39 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Claim 1, "outer ring defines an **undulating**, contoured end surface" is not supported in the specification. End surface is believed to the axial end and not the outer circumference which is circular as shown in figure 3. No new matter can be added.

Allowable Subject Matter

Claim 38 is allowed.

Claims 22-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-6, 8-13, 15-21, 25-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnson et al (2004/0024451).

Johnson et al teaches a flexible sizer body

A continuous outer ring characterized by the absence of a cloth cover; and

an annular wall coupled to and extending from the outer ring, wherein the

annular wall forms a plurality of extremities adapted to be inwardly deflected;

Art Unit: 3738

wherein the outer ring defines an undulating, contouring end surface of the sizer body.

It is noted that Johnson et al teaches the outer ring has a cover 32, however, there is no teaching that the cover is cloth.

Regarding claim 20, see at least figure 19 teaching a handle.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8-13, 15-21, 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lam et al (WO 97/25003) in view of Love et al (2002/0020074) and, when necessary, further in view of Rhee (6,350,281).

Lam et al teaches a sizer body for evaluating a valve annulus to determine a size of a prosthetic heart valve to be sewn to the valve annulus during heart valve replacement surgery, flexible sizer body comprising:

a handle extending proximally from the sizer body;

a continuous undulating outer ring 18;

an annular wall 14 coupled to and extending from the outer ring,

however, Lam et al fails to teach the annular wall forms a plurality of extremities adapted to be inwardly deflected. Love et al teaches a similar sizing device having this feature. It would have been obvious to one having ordinary skill in the art to have formed the annular wall 14 of Lam et al having a plurality of extremities as taught by Love et al such that the sizer "corresponds to the geometry of the normal native valve leaflet anatomy" (paragraph 5) and "substantially conforming to the shape of the contouring line of the valve leaflet attachment to the annulus" (paragraph 8).

It is noted that Love et al "sufficient rigidity to maintain its shape" when used, therefore, having some degree of flexibility.

If necessary, Rhee also teaches a sizing device wherein the outer ring is flexible and has the resiliency substantially equal to the resiliency of the sewing ring of the artificial heart valve. Rhee additionally teaches the annular wall can be resilient and formed as a one-piece design with the outer ring, therefore, also being an elastomeric material. Also see claim 14 teaching flexibility. It would have been obvious to one having ordinary skill in the art to have utilized the teachings of Rhee et al having a flexible sizer utilizing the materials, etc. on the combination sizer of Lam et al and Love et al such that the sizer can mimic the physical characteristics of an artificial valve with a sewing ring 4:2-4.

Claims 1-6, 8-13, 15-21, 25-28 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Johnson et al (2004/0024451).

Johnson et al teaches a flexible sizer body comprising: a continuous outer ring characterized by the absence of a cloth cover; and
an annular wall coupled to and extending from the outer ring, wherein the annular wall forms a plurality of extremities adapted to be inwardly deflected;
wherein the outer ring defines an undulating, contouring end surface of the sizer body.

Regarding claim 20, see at least figure 19 teaching a handle.

It is noted that Johnson et al teaches the outer ring has a cover 32, however, there is no teaching that the cover is cloth. This is interpreted as "absence of a cloth cover".


In the alternative, it is well known in the art to utilize different types of coverings over the outer ring other than cloth such as pericardium or PTFE; it would have been obvious to one having ordinary skill in the art to utilize one of these covering materials on the outer ring of Johnson et al for their well known biocompatibility, availability, etc.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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BRUCE SNOW
PRIMARY EXAMINER